IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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Attorneys for Plaintiffs,
MERCK & CO., INC., and
MERCK SHARP & DOHME CORP.

MERCK & CO., INC., and MERCK SHARP & DOHME CORP. Plaintiffs, v. TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	CIVIL ACTION NO.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck & Co., Inc. and Merck Sharp & Dohme Corp. (hereinafter "Plaintiffs"), by way of Complaint against Teva Parenteral Medicines, Inc., Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries, Ltd. allege as follows:

THE PARTIES

1. Merck & Co., Inc. is a corporation organized and existing under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889. Merck & Co., Inc. is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

2. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc., and is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

3. On information and belief, Teva Parenteral Medicines, Inc. ("Teva Parenteral") is incorporated under the laws of the state of Delaware.

4. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva USA") is a corporation incorporated under the laws of the state of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454, and conducting business from facilities at 18-01 River Road, Fair Lawn, New Jersey 07410 and 8-10 Gloria Lane, Fairfield, New Jersey 07004.

5. On information and belief, Teva Pharmaceutical Industries, Ltd. ("Teva Israel") is a corporation organized and existing under the laws of Israel, having its corporate headquarters at 5 Basel Street, P.O.B. 3190, Petach Tikva 49131, Israel.

6. On information and belief, Teva Parenteral is a wholly-owned subsidiary of Teva USA. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Israel.

7. On information and belief, Teva Parenteral and Teva USA are in the business of developing and manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

8. On information and belief, Teva Parenteral assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j), Abbreviated New Drug Application ("ANDA") No. 91-598 concerning a proposed generic drug product, Caspofungin Acetate for Injection, 50 mg/vial and 70 mg/vial.

9. On information and belief, Teva Israel assembled and caused to be filed with the FDA Drug Master File No. 22770 on May 12, 2009 concerning caspofungin manufacturing.

10. On information and belief, Teva Israel and Teva USA, acting alone or in concert, caused, actively encouraged, and/or directed Teva Parenteral to file ANDA No. 91-598 with the FDA, and/or participated in the work related to the submission of ANDA No. 91-598.

11. Teva Parenteral, Teva USA, and Teva Israel are referred to hereinafter, collectively, as "Teva."

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

13. Teva Parenteral and Teva USA are subject to jurisdiction in New Jersey because they manufacture pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within New Jersey.

14. Teva Parenteral and Teva USA are subject to personal jurisdiction in New Jersey because they regularly and systematically conduct business within New Jersey and Teva USA has offices within New Jersey.

15. Teva Israel is subject to personal jurisdiction in New Jersey because it manufactures pharmaceuticals and pharmaceutical products that are sold and used, including by Teva USA and Teva Parenteral, throughout the United States, including within New Jersey.

16. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c), (d) and 28 U.S.C. § 1400(b).

CANCIDAS®

17. Merck & Co., Inc. holds approved new drug application ("NDA") 21-227 for CANCIDAS®, the active ingredient of which is caspofungin acetate. CANCIDAS® is approved for the treatment of certain types of fungal infections.

18. Merck Sharp & Dohme Corp. is the owner of U.S. Patent No. 5,378,804 ("the '804 patent"), U.S. Patent No. 5,514,650 ("the '650 patent"), and U.S. Patent No. 5,952,300 ("the '300 patent") (Patents attached as Exhibits A, B and C, respectively).

19. CANCIDAS® is an embodiment of one or more claims of each of the '804, '650, and '300 patents.

TEVA ANDA

20. On or about October 22, 2009, Merck & Co., Inc. received from Teva Parenteral a letter, dated October 21, 2009 (the "October 21 letter"), stating that Teva Parenteral

had submitted an ANDA, assigned as No. 91-598, to the FDA to seek approval to market caspofungin acetate for injection, in 50 mg/vial and 70 mg/vial forms ("the Teva Products").

21. In its October 21 letter, Teva Parenteral stated that, in its ANDA, it had included certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that each of the '804, '650, and '300 patents is invalid, unenforceable, or would not be infringed by the manufacture, use, or sale of the Teva Products.

22. The Teva ANDA refers to and relies upon the Merck & Co., Inc. NDA and contains data that, according to Teva, demonstrates the bioequivalence of the Teva Products and CANCIDAS®.

INFRINGEMENT OF U.S. PATENT NO. 5,378,804

23. Plaintiffs repeat and reallege paragraphs 1-22 above as if fully set forth herein.

24. By filing its ANDA No. 91-598 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Teva Products before the expiration of the '804 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

25. If Teva commercially makes, uses, offers to sell, or sells the Teva Products within the United States, or imports the Teva Products into the United States, or induces or contributes to any such conduct during the term of the '804 patent, it would further infringe the '804 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

26. Merck will be irreparably harmed if Teva is not enjoined from infringing the '804 patent. Merck does not have an adequate remedy at law.

27. Teva's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '804 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

INFRINGEMENT OF U.S. PATENT NO. 5,514,650

28. Plaintiffs repeat and reallege paragraphs 1-22 above as if fully set forth herein.

29. By filing its ANDA No. 91-598 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Teva Products before the expiration of the '650 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

30. If Teva commercially makes, uses, offers to sell, or sells the Teva Products within the United States, or imports the Teva Products into the United States, or induces or contributes to any such conduct during the term of the '650 patent, it would further infringe the '650 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

31. Merck will be irreparably harmed if Teva is not enjoined from infringing the '650 patent. Merck does not have an adequate remedy at law.

32. Teva's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '650 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

INFRINGEMENT OF U.S. PATENT NO. 5,952,300

33. Plaintiffs repeat and reallege paragraphs 1-22 above as if fully set forth herein.

34. By filing its ANDA No. 91-598 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Teva Products

before the expiration of the '300 patent, Teva committed an act of infringement under 35 U.S.C. § 271(e)(2).

35. If Teva commercially makes, uses, offers to sell, or sells the Teva Products within the United States, or imports the Teva Products into the United States, or induces or contributes to any such conduct during the term of the '300 patent, it would further infringe the '300 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

36. Merck will be irreparably harmed if Teva is not enjoined from infringing the '300 patent. Merck does not have an adequate remedy at law.

37. Teva's certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) against the '300 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request:

A. Judgment that Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., and Teva Pharmaceutical Industries, Ltd. have infringed one or more claims of the '804 patent by filing ANDA No. 91-598 relating to Teva's generic caspofungin acetate products;

B. A permanent injunction restraining and enjoining Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., and Teva Pharmaceutical Industries, Ltd. and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic caspofungin products as claimed in the '804 patent;

C. An order that the effective date of any approval of ANDA No. 91-598 relating to Teva's generic caspofungin acetate products be a date that is not earlier than the

expiration date of the '804 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

D. Judgment that Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., and Teva Pharmaceutical Industries, Ltd. have infringed one or more claims of the '650 patent by filing ANDA No. 91-598 relating to Teva's generic caspofungin acetate products;

E. A permanent injunction restraining and enjoining Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., and Teva Pharmaceutical Industries, Ltd. and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic caspofungin products as claimed in the '650 patent;

F. An order that the effective date of any approval of ANDA No. 91-598 relating to Teva's generic caspofungin acetate products be a date that is not earlier than the expiration date of the '650 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

G. Judgment that Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., and Teva Pharmaceutical Industries, Ltd. have infringed one or more claims of the '300 patent by filing ANDA No. 91-598 relating to Teva's generic caspofungin acetate products;

H. A permanent injunction restraining and enjoining Teva Pharmaceuticals USA, Inc., Teva Parenteral Medicines, Inc., and Teva Pharmaceutical Industries, Ltd. and their officers, agents, attorneys and employees, and those acting in privity or concert with them, from

engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of generic caspofungin products as claimed in the '300 patent;

I. An order that the effective date of any approval of ANDA No. 91-598 relating to Teva's generic caspofungin acetate products be a date that is not earlier than the expiration date of the '300 patent plus any other regulatory exclusivity to which Plaintiffs are or become entitled;

J. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, expenses, and disbursements of this action; and

K. Such other and further relief as the Court may deem just and proper.

Dated: November 25, 2009

Respectfully submitted,

By: s/ Sheila F. McShane

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